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Antonio Ricci

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MCGLEW & TUTTLE, PC  
P.O. BOX 9227  
SCARBOROUGH STATION  
SCARBOROUGH, NY 10510-9227

EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/581,964	RICCI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sally A. Sakelaris	1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/7/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's election with traverse of Group I in the reply filed on 8/13/2008 is acknowledged. The traversal is on the ground(s) that the method of Group II requires the special technical feature of Group I. This is not found to be persuasive because as was shown in the restriction requirement, the common element linking the groups was known in the prior art and as a result cannot be considered a special technical feature able to link the 2 groups. The applicant further argues that a single search can be made to consider all aspects of Groups I and II. This is not found to be persuasive as the search of the method and product is not coextensive since the two inventions would be classified variously in Class 422 (device) and Class 436 (method) for example therefore causing a burden on the office and the examiner.

The requirement is still deemed proper and is therefore made FINAL.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “fixed guides”, “mobile guides”, “sliding shoes” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-17, 21-28, and 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Skotnikov et al. (US 5526705).

Applicant should note that the recitation in the preamble for measuring sedimentation rate in biological samples and in especially blood samples has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The prior art has been applied appropriately.

With regard to claims 1 and 44, Skotnikov et al. in Figure 1 teach holders (i.e., links in the belt (36) Col. 10 line 20-22) for test tubes (vessels (32) containing samples of biological fluids; agitator devices (40, 50, 100) for agitating said test tubes (32); at least one detector (78, 180 as an example) for detecting the levels inside said test tubes; characterized in that wherein said holders (links in the belt sized to snugly fit about an outer perimeter of vessels 32) are formed in a continuous flexible member (Figure 3) defining a closed path, along which said agitator devices (Figure 1 40, 50 and 100) and said at least one detector (78, Fig.1) are arranged.

With regard to claim 2, Skotnikov et al. teaches agitators (40, 50, and 100) (Col. 4 lines 16-22). 100 is taught to be a dedicated stirrer (Col. 6 line 50).

With regard to claims 3 and 41, Skotnikov et al. teach the following are arranged along the closed path of the device: one agitating area (Fig. 1, 45, 50, 100) at least one sedimentation area (following each of 45, 50, and 100 in Fig. 1); And at least one reading area wherein said detector is installed (78 in Fig. 1).

With regard to claims 4, 42, and 43, the flexible member (36) lies along a horizontal plane.

With regard to claims 5-9, Skotnikov teach that the holders represent the links that fit each outside perimeter of each vessel (Col. 10) and further that within these links oscillation (i.e. agitation) is possible at various locations (stations) within the device (e.g. 40, 50, 100) outside the plane on which the flexible member lies.

With regard to claim 10-15, Skotnikov teach agitators (i.e. 40, 50, 100 and sprockets (140) Fig. 3) that act as guides. The intersection with the conveyor holders can be viewed as “sliding shoes” and are slidingly engaged in the absence of a figure showing that which applicant intends to be claiming with this recitation. Skotnikov also teach agitating fixed guides in the form of sprockets 140 (rotor coaxial in Fig. 3) and mobile guides that are arranged to induce agitation in the form of 40, 50, and 100. The sprockets are shown in Fig 3 to be provided with elements for engaging the holders and capable of rotating around its own axis.

With regard to claims 16 and 17, Skotnikov teach FIG. 1 that is a schematic representation of automated work station 10 according to the present invention. Automated work station 10 includes sample preparation station (or line) 12 and a plurality of test stations, or testing lines A, B, C, D, F, G, H and J each with various detectors. Test station A determines soil acidity, test station B determines soil carbon content, test station C is used to prepare a soil extract which is eventually provided to ion-selective flow sensors for the determination of nutrients and micronutrients in the sample, test station F determines alkali soluble fraction of organic matters, test station G is used to determine organic matter, test station H is used to determine sesquioxides, and test station J is used to determine dust, sand and physical clay in the sample. Various detectors (i.e., sensors) in the testing lines are coupled to controller interface 14 which is, in turn, coupled to controller 16.

With regard to claims 21-28, applicant should note that a recitation of the intended use such as those recited for the automatic manipulator of the claimed invention must result in a structural difference between the claimed invention and the

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prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With regard to claim 21, Skotnikov teach a robotic manipulator that removes vessels 32 from their holders in the conveyor 36 and replaces vessels 32 in conveyor 36 (Column 10 lines 48-50).

With regard to claims 22-24, Skotnikov teach that separate robotic manipulators are used in line D and in test line J (Col. 10 line 60-61). Therefore there are 2 extractors taught that are capable of moving tubes into and out of the holder.

With regard to claims 25 and 26, Skotnikov teach a setup unit (i.e., a sample prep line (12)) that is above the continuous flexible member (Fig. 1 (36)).

With regard to claims 27 and 28, Skotnikov teach a controlling unit 16 that receives readings from the reading station, i.e., the humidity meter 28 (Col. 3 lines 45-52).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Kaarakainen et al (US 6520313).

The teachings of Skotnikov et al can be seen above.

Skotnikov do not teach a transponder being associated with each holder and test tube, nor do they teach stations for scanning these transponders.

With regard to claims 18-20, Kaarakainen et al. teach transport bases or holders for test tubes (Fig. 1) that incorporate an RF memory circuit, in which data can be entered and read without contact in, for example, a control station, which can then decide which processing point to transfer the holder with test tube to (Col. 3 lines 1-3). Kaarakainen et al goes on to teach that the RF memory circuit, i.e., transponder can be read rapidly and as the small read/write sensor can be located almost anywhere, its location does not restrict the mechanical design of the system (Col. 3 lines 35-38).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to have incorporated the RF transponders and scanners of Kaarakainen et al into the device of Skotnikov et al. as Kaarakainen et al. provide the motivation that the transponders can be read rapidly and that the scanners can be located anywhere in the device which would allow for more efficient processing of samples and would avoid errors due to misidentification of the tubes within their holders.



3. Claims 29-30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. (US 4609017).

The teachings of Skotnikov et al can be seen above.

Skotnikov do not teach a setup unit that comprises a first and second transfer unit with a first and second conveyor for moving a plurality of racks containing test tubes, and a reading unit associated with one of the two.

With regard to claims 29-30 and 32-34, Coulter teach in Figure 2 a setup unit that can be retrofit to an analyzer consisting of a plurality of racks (12) which are stacked vertically above a first conveyor (i.e., input elevator (20)) Col. 4 lines 23-64. The racks are stripped one at a time from the bottom of the stack within the first transfer unit (16) and lowered by the first conveyor (i.e., elevator (20)) onto the second conveyor belt (32) and tilt table en route to the second transfer unit (40). Also, a reading unit is taught within this setup unit there at a time and place during, or just prior to sample aspiration, the identification of the sample is read (50) automatically for correlation with that sample's parameter measurements Col 8, lines 50-68).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to have incorporated the features of Coulter's setup unit into the setup unit of Skotnikov et al. as Coulter teaches his sample setup unit (i.e., sample carrier transport system) is capable of being housed in a stand-alone module, with the aspirated sample then being fed from this module into the main body of the analyzer and furthermore that such module configuration would be useful for retrofit with other styles of analyzers, such as one of Skotnikov et al. for example. Furthermore, the benefit exists

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that in Coulter's setup unit many samples may be handled in parallel without a manual step creating a more efficient, high throughput device.

4. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. (US 4609017) and in further view of Roginski (US 4927545).

The teachings of Skotnikov can be viewed above.

Skotnikov et al. do not teach that their robotic manipulators include a lower push bar coming to bear on the test tubes contained in the racks in order to slide said test tubes partially out of said racks and furthermore a mobile clamp for removing the test tubes from the racks and inserting them into corresponding holders in the continuous flexible member.

Coulter et al. teach in Figure 4 and Figure 2 manipulators that include a lower push bar (42) coming to bear on the test tubes contained in the racks in order to slide said test tubes partially out of said racks (Col. 6 lines 49-53).

Coulter et al do not teach a mobile clamp for then removing the test tube from the rack and inserting them into a holder of the continuous flexible member.

Roginski teach in Figure 1 and in claim 12 that a robotic arm adapted to move the test tubes in a variety of ways one by one from a first location to a second. For example the robotic arm (10) with mobile clamp (14) is adapted to remove the test tubes, one at a time, from said input station and move them to the centrifuge, remove the centrifuged test tubes and place them in the optical inspection station, and remove the optically inspected test tubes and place them into either said first or second output station under control of

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the means for evaluating the electrical signals to determine the success of the separation operation.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to have incorporated the features of Coulter's tube pusher and Roginski's robotic arm into the "robotic manipulator" (Col. 10) of Skotnikov et al. and subsequently into Skotnikov's conveyor device as both the tube pusher of Coulter and Robotic clamp arm of Roginski allow for specialized treatment of each test tube sample adding specificity to a high throughput system achieving therein a flexible and scalable device capable of operating on both micro and macro levels.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 5712726297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sally Sakelaris

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797